UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ARATANA THERAPEUTICS INC. SECURITIES LITIGATION

17 Civ. 880 (PAE)

OPINION & ORDER

PAUL A. ENGELMAYER, District Judge:

In this putative class action arising under the federal securities laws, lead plaintiffs Joseph Bessent, John Corbitt, and Eric Pearson claim that animal pharmaceutical company Aratana Therapeutics, Inc. ("Aratana") and two of its officers, Steven St. Peter and Craig A. Tooman, made false and misleading statements or omissions regarding the future commercial availability of "ENTYCE," an appetite stimulant for dogs. Plaintiffs bring this lawsuit on behalf of all persons (other than defendants) who purchased Aratana securities between March 16, 2015 and March 13, 2017 (the "Class Period"). They allege violations of §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and the corresponding rule of the Securities and Exchange Commission, 17 C.F.R. § 240.10b-5 ("Rule 10b-5").

Pending now is Aratana's motion to dismiss the Amended Class Action Complaint ("AC") for failure to state a claim under Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the Court grants the motion and dismisses the AC in its entirety.

I. Background[1]

A. The Parties

[1] These facts are drawn primarily from the AC. Dkt. 22. For the purpose of resolving the motion to dismiss, the Court assumes all well-pled facts to be true and draws all reasonable inferences in favor of plaintiffs. *See Koch v. Christie's Int'l PLC*, 699 F.3d 141, 145 (2d Cir. 2012). The Court has also considered the documents attached to the declaration of Kevin M. McDonough in support of the motion to dismiss, Dkt. 30 ("McDonough Decl."), and the document attached to the declaration of Shannon L. Hopkins in opposition to the motion to dismiss, Dkt. 32 ("Hopkins Decl."). Because these documents were incorporated into the AC by reference, or are matters of

Aratana is "a development-stage biopharmaceutical company that develops biomedical therapeutics for animals." AC ¶ 2. The individual defendants are St. Peter, Aratana's President, CEO, and founder, and Tooman, Aratana's CFO and Treasurer. *Id.* ¶¶ 23–24. Each exercised authority with respect to Aratana's conduct, and each had access to material inside information about Aratana during the Class Period. *Id.*

The lead plaintiffs are individuals who acquired Aratana securities during the Class Period. *Id.* ¶¶ 19–21.

B. Aratana's Business Activities During the Class Period

At the start of the Class Period—March 16, 2015—Aratana had two animal pharmaceutical products conditionally or fully approved by either the Food and Drug Administration ("FDA") or the United States Department of Agriculture ("USDA"): BLONTRESS and TACTRESS, which are both lymphoma treatments for dogs. *Id.* ¶¶ 29, 55. The company received full approval for BLONTRESS in early 2015, and for TACTRESS in January 2016. *Id.* ¶ 61.

In October 2015, Aratana entered into a loan agreement consisting of a $35 million term loan and a $5 million revolving line of credit. *Id.* ¶ 4. The loan agreement provided that certain payment obligations would be deferred if, by December 31, 2016, Aratana had received full

---

public record, they are properly considered on a motion to dismiss. *See City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 179 (2d Cir. 2014) (in resolving a motion to dismiss, the court may consider, *inter alia*, "any statements or documents incorporated in it by reference, as well as public disclosure documents required by law to be, and that have been, filed with the SEC, and documents that the plaintiffs either possessed or knew about and upon which they relied in bringing the suit"). The Court considered these documents "not for the truth of the matters asserted therein," but only "for the fact that the statements were made." *Clark v. Kitt*, No. 12 Civ. 8061(CS), 2014 WL 4054284, at *7 (S.D.N.Y. Aug. 15, 2014); *see also, e.g.*, *Staehr v. Hartford Fin. Servs. Grp.*, 547 F.3d 406, 425 (2d Cir. 2008) ("[I]t is proper to take judicial notice of the fact that press coverage, prior lawsuits, or regulatory filings contained certain information, without regard to the truth of their contents." (emphasis omitted)).

regulatory approval for four biomedical products (including BLONTRESS and TACTRESS), as well as conditional approval for a fifth. *Id.* Receiving this deferment was "critical to [Aratana's] future viability." *Id.*

In March 2016, the company received full approval for a third product: GALLIPRANT, an arthritis treatment for dogs. *Id.* ¶¶ 28, 61. On May 16, 2018, the company received full approval for ENTYCE, the product at issue in this lawsuit. *Id.* ¶ 62. Finally, in August 2016, Aratana received full approval for NOCITA, a pain medication for dogs. *Id.* ¶ 63. With NOCITA's approval, Aratana met the terms of the loan agreement. *Id.*

C. The FDA Approval Process

Plaintiffs' claims concern defendants' statements about the FDA approval process for (and subsequent commercial distribution of) ENTYCE. ENTYCE, also known as AT-002, is a "capromorelin oral solution" designed to stimulate appetite in dogs suffering from acute and chronic diseases. *Id.* ¶ 48. Commercial distribution of an animal pharmaceutical like ENTYCE requires FDA approval. *Id.* ¶¶ 29, 40. That process involves several steps, as follows.

First, a company seeking approval for an animal pharmaceutical must establish an Investigational New Animal Drug file with the FDA's Center for Veterinary Medicine ("CVM"). *Id.* ¶ 42. The company then holds a pre-development meeting with the CVM to establish a plan for providing data necessary to meet the requirements for a New Animal Drug Application ("NADA"). *Id.*

As part of the NADA process, the company must gather and submit data on three "technical sections," each of which must be satisfied to receive approval: (1) safety; (2) effectiveness; and (3) chemistry, manufacturing, and controls ("CMC"). *Id.* ¶¶ 43–44. As to the CMC section specifically, the company must demonstrate that the product has a "defined

manufacturing process that ensures that the product can be made with high quality consistency." *Id.* ¶ 43 (quotation marks omitted). Manufacturing may take place in-house, or, as with Aratana, with the assistance of third-party "contract manufacturers" compliant with Current Good Manufacturing Practices ("cGMP"). *Id.* ¶¶ 35–36.[2]

If the CVM deems the company's submissions satisfactory as to any particular technical section, it issues a technical section complete letter for that section. *Id.* ¶ 44. Once the company receives all three letters, it then files an "administrative NADA," which compiles certain additional relevant information, including proposed labeling. *Id.* ¶ 45. Generally, if there are no deficiencies in the administrative NADA, the FDA will fully approve the product within 60 days. *Id.*

Once a drug is approved, any post-approval changes that may adversely affect the identity, strength, quality, purity, or potency of a drug are deemed "major changes," and require renewed approval by the CVM. *Id.* ¶ 46. Relevant here, a change in manufacturing sites constitutes a major change if the new site has never been inspected by the FDA for the relevant type of operation, or if the new site does not comply with cGMP. *Id.* To secure approval for a major change, and thus to receive authorization to distribute any products affected by the change, a company must file a Prior Approval Supplement ("PAS"). *Id.* A PAS is subject to a 120-day review period. *Id.*

---

[2] Aratana used contract manufacturers because it "lack[ed] the resources and capability to manufacture any of [its] own therapeutic candidates on a scale necessary for commercialization." *Id.* ¶ 35 (quotation marks omitted). Thus, as Aratana disclosed, the company was "completely dependent on [contract manufacturers] to comply with cGMP [and] ha[d] no control over the [contract manufacturers'] ability to maintain adequate quality control and quality assurance practices." *Id.* ¶ 36.

D. Aratana's Challenged Statements Regarding ENTYCE

By March 16, 2015—the start of the Class Period—Aratana had already submitted a NADA to the CVM regarding ENTYCE, and had already received a technical section complete letter for the safety section. *See id.* ¶ 49. Plaintiffs allege that from that date until March 13, 2017, defendants made a series of false and misleading statements or omissions concerning ENTYCE's prospects for commercialization. Specifically, plaintiffs allege that defendants falsely stated that ENTYCE was on track for commercial launch first in 2016 and then in early 2017, while in fact defendants knew that these timelines were unrealistic, given that Aratana had failed to secure an FDA-approved manufacturer capable of producing ENTYCE on a commercial scale. *Id.* ¶¶ 6, 13. According to plaintiffs, the truth was finally revealed to investors on February 6, 2017, when Aratana disclosed that the CVM had, on February 2, 2017, requested additional information regarding the company's transfer of manufacturing for ENTYCE from one vendor to another. *Id.* ¶¶ 10–11.[3]

The Court will now recite chronologically the statements alleged by plaintiffs to be actionably false or misleading and to have supported defendants' scheme. For ease of reference, the Court has grouped the alleged misstatements by expected commercialization date—*i.e.*, the anticipated commercial release date for ENTYCE as announced by defendants.[4]

1. Anticipated 2016 or "Mid-2016" Release

On March 16, 2015, having received the first section complete letter for ENTYCE, Aratana filed its annual Form 10-K with the SEC. *Id.* ¶ 73. This submission marks the

---

[3] The Class Period is defined as lasting until March 13, 2017, on the theory that the full extent of the financial harm caused by this delay had not come into focus until then. *See id.* ¶ 118.

[4] Certain statements are inaccurately transcribed in the AC. The Court recites here the original language from the underlying documents.

beginning of the Class Period. Plaintiffs claim that several of defendants' statements in this document were false and misleading. Because this document (like later, similar Forms 10-K filed by Aratana) is central to the instant motion to dismiss, the Court describes the Form at some length.

The Form begins with a series of cautionary statements. First, Aratana identified as "forward looking," for purposes of the Private Securities Litigation Reform Act of 1995, any statements concerning "management's plans and objectives for product development and commercialization," "anticipated timing of regulatory submissions and approvals," and "business prospects and collaborations." McDonough Decl. Ex. 13 at 1 (the "2014 10-K"). Such statements, the Form warned, were subject to "risks, uncertainties and assumptions, that, if they never materialize or if they prove incorrect, could cause our consolidated results to differ materially from those expressed or implied by such forward-looking statements." *Id.*

The report then directed readers to a set of "Risk Factors." *See id.* As relevant here, these included the following:

- "Although we have one fully approved product and one conditionally approved product, we are substantially dependent on the success of our current product candidates." *Id.* at 33.
- "The development and commercial success of our current product candidates will depend on a number of factors, including . . . the ability of us or our third-party manufacturers to manufacture supplies of any of our current or future product candidates and to develop, validate and maintain commercially viable manufacturing processes that are compliant with [cGMP, and] our ability to successfully launch commercial sales of our current product candidates, assuming CVM . . . approval is obtained, whether alone or in collaboration with others . . . ." *Id.* at 33–34.
- "We may be unable to obtain regulatory approval for our existing or future product candidates under applicable regulatory requirements. The denial or delay of any such approval would delay commercialization efforts and adversely impact our potential to generate revenue, our business and our results of operations." *Id.* at 34.

- "We rely completely on third-party manufacturers to manufacture the supplies for the development of [products such as ENTYCE] and we intend to rely on third-party manufacturers to produce commercial quantities of any of these approved drug candidates. With respect to [these products], we do not currently have, nor do we currently plan to acquire, the internal infrastructure or capability to manufacture . . . any of our product candidates on a scale necessary for commercialization. We will need to identify contract manufacturers to provide commercial supplies of the formulated drugs . . . . If the CVM . . . does not approve our contract manufacturers' facilities used for the manufacture of our product candidates, or if any such agency withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop and obtain regulatory approval for or market our product candidates, if approved." *Id.* at 38–39.

- "[T]o manufacture our product candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers may need to increase manufacturing capacity, which could involve significant challenges and may require additional regulatory approvals. Neither we nor our third-party manufacturers may successfully complete any manufacturing scale-up activities required to increase existing manufacturing capabilities in a timely manner, or at all." *Id.* at 39; *see also* AC ¶ 105.

The Form also included statements about the business prospects of Aratana's product candidates. Noting that "[m]anufacturers of animal health pharmaceuticals, including us, must show their products to be safe, effective and produced by a consistent method of manufacture," Aratana stated that it had "established processes and resources to provide oversight of the development and launch of our products and their maintenance in the market." AC ¶ 102; 2014 10-K at 24, 28. With respect to ENTYCE specifically, the Form stated "[w]e plan to have all three major technical sections of the NADA completed in time to receive NADA approval in 2016." *Id.* ¶ 73; 2014 10-K at 11.

On May 8, 2015, Aratana filed a quarterly Form 10-Q with the SEC, in which the company "anticipate[d] U.S. marketing approval [for ENTYCE] in 2016." AC ¶ 74; McDonough Decl. Ex. 17 at 21 (the "Q1 2015 10-Q"). That same day, the company held an

earnings call, in which St. Peter stated that "Aratana is working to secure commercial supply" of ENTYCE. AC ¶ 75; McDonough Decl. Ex. 18 at 4 (the "Q1 2015 Earnings Call").[5]

On August 6, 2015, Aratana issued a press release attached to a Form 8-K updating the market on recent positive ENTYCE study results. It noted that "Aratana anticipates submitting an administrative [NADA] for [ENTYCE] in 2016, which if approved, would allow the Company to commence commercialization of the product in mid-2016." AC ¶ 76; McDonough Decl. Ex. 19 at 1.

On August 7, 2015, Aratana filed its second-quarter 2015 Form 10-Q. AC ¶ 77. As concerns ENTYCE, Aratana reported that it "anticipate[d] submitting an NADA for AT-002 in dogs in 2016, which if approved, would allow us to commence commercialization of the product in mid-2016." *Id.*; McDonough Decl. Ex. 5 at 21 (the "Q2 2015 10-Q").

The same day, Aratana held another earnings call. St. Peter stated that "Aratana has made remarkable progress towards our stated goal of advancing our expanding pipeline towards commercialization." AC ¶ 79; McDonough Decl. Ex. 4 at 3 (the "2015 Q2 Earnings Call"). He continued: "One implication of this substantial progress, Aratana believes that it will have six products on the market in 2016. . . . [T]hat has been the planning assumption for quite some time." AC ¶ 79; 2015 Q2 Earnings Call at 3–4. In response to a question regarding what Aratana was "doing to prepare for manufacturing and supply needs for [ENTYCE]," St. Peter responded: "[W]e're working to complete the commercial supply agreement on that one." AC ¶ 79; 2015 Q2 Earnings Call at 8. As to that subject, he continued, it is something "we've been

[5] Like every document alleged by plaintiffs to contain false or misleading statements, these two documents—the Q1 2015 10-Q and the Q1 2015 Earnings Call transcript—expressly incorporate the risk factors identified by Aratana in its Form 10-K. *See* Q1 2015 10-Q at 29; Q1 2015 Earnings Call at 3. Likewise, every document referenced in the AC contains an express forward-looking statement disclaimer. *See, e.g.*, Q1 2015 10-Q at 20; Q1 2015 Earnings Call at 3.

working on and tracking to support the launch of the products in 2016. But it will be contract manufacturing." AC ¶ 79; 2015 Q2 Earnings Call at 8.

On September 24, 2015, Aratana issued another press release attached to a Form 8-K. The company stated that it "anticipate[d] submitting an NADA in early 2016, which if approved, is expected to enable the Company to commence commercialization of the product in mid-2016 or," as the company suggested for the first time, "shortly thereafter." AC ¶ 80; McDonough Decl. Ex. 20 at 1.

On November 5, 2015, Aratana issued another press release, also attached to a Form 8-K. The company announced that it had received its technical section complete letter for ENTYCE for CMC. AC ¶ 81; McDonough Decl. Ex. 21 at 1. The press release set out the same timeline and noted, with respect to ENTYCE, that "[c]learly, in the near-term, the key priority is commercial execution." AC ¶ 81; McDonough Decl. Ex. 21 at 1, 3 (quotation marks omitted).

On November 6, 2015, in its third-quarter 2015 Form 10-Q, Aratana set forth the same timeline with the same language. AC ¶ 82; McDonough Decl. Ex. 22 at 28 (the "2015 Q3 10-Q"). And on a November 6, 2015 earnings call, St. Peter stated: "[W]e are proud of the fact that 2.5 years later we believe that we are on track to have these products [including ENTYCE] reach the market in 2016 . . . . We very much look forward to launching these products next year." AC ¶ 83; McDonough Decl. Ex. 23 at 3 (the "2015 Q3 Earnings Call"). St. Peter added that the company was "confident in these products and our overall commercialization strategy." AC ¶ 83; 2015 Q3 Earnings Call at 3. Finally, as to the "unprecedented number of pet therapeutics" that Aratana hoped to have on the market by 2016, St. Peter stated that Aratana had already "completed safety studies, demonstrated GMP manufacturing, conducted pilot field studies and

successfully completed the rigorous pivotal field effectiveness studies." AC ¶ 103; 2015 Q3 Earnings Call at 3.

On November 17, 2015, Aratana filed a Form 8-K. It stated that the company "plan[ned] to have discussions with the national veterinary distributors in the first and second quarters of 2016 to discuss potential distribution arrangements for our product candidates." AC ¶ 84; McDonough Decl. Ex. 24 at 3.

2. Anticipated Late-2016 Release

On March 14, 2016, Aratana issued a press release attached to a Form 8-K. It announced that Aratana had received its third and final technical section complete letter for ENTYCE (for effectiveness). AC ¶ 85; McDonough Decl. Ex. 6 at 4. Aratana stated that it was "finalizing the [ENTYCE] product label, completing the other minor sections, and expect[ed] to submit the administrative NADA by the end of March 2016." AC ¶ 85; McDonough Decl. Ex. 6 at 4. As for commercialization, the company revised its timeline: Aratana now "anticipate[d] commercial availability of ENTYCE in late-2016 or shortly thereafter." AC ¶ 85; McDonough Decl. Ex. 6 at 4.

On March 15, 2016, Aratana filed its 2015 Form 10-K. It stated Aratana's expectation, pending CVM approval, of "commenc[ing] commercialization of ENTYCE in the United States in late-2016 or shortly thereafter." AC ¶ 86; McDonough Decl. Ex. 2 at 6 (the "2015 10-K"). Relevant here, Aratana also stated as follows:

> We have identified contract manufacturers to provide commercial supplies of the APIs [*i.e.*, active pharmaceutical ingredients] and formulated drugs for our lead pharmaceutical product candidates [including ENTYCE]. These contract manufacturers have established track records of quality product supply and significant experience with regulatory requirements of both CVM and [the European Medicines Agency]. We are currently transferring the manufacturing technology process for . . . ENTYCE and scale-up required for commercialization.

> We believe we have or will have sufficient supply of formulated drugs to meet our commercial forecast.

AC ¶ 87; 2015 10-K at 9.[6]

That same day, Aratana held another earnings call with analysts. *See* AC ¶ 88; McDonough Decl. Ex. 7 (the "2015 Q4 Earnings Call"). On that call, an analyst asked whether and to what extent manufacturing processes were "driving the timing" of the commercialization of products such as ENTYCE. *See* AC ¶ 88; 2015 Q4 Earnings Call at 6. St. Peter responded as follows:

> So a number of things create that time between when you get the formal approval and when you actually launch the product. One of which is you actually have to really create a commercial supply with the product labeling and all of the different SKUs for the products. So that you can actually stock if you're going to use distributors, you can stock the distributors and also make the product available. So one issue is just that ramping up the commercial supply and inventory to launch. One of the others is the conference sequence and really thinking about when you want to be launching and obviously, between holidays is not ideal. . . . And the other challenge that we have obviously is commercial scale up. You run the clinical trials with smaller batches of products. That's what the approval is based on. Then as you move to commercialization, you scale that up to support really a commercial product. And so we're doing that with respect to both Galliprant and Entyce. . . . [W]ith respect to [those products], we're seeking to enter those supply agreements to really support the overall commercial forecast.

AC ¶ 88; 2015 Q4 Earnings Call at 6. The analyst followed up, "just to clarify that last point, are you still working on those commercial agreements or are those already in place at this point?" AC ¶ 88; 2015 Q4 Earnings Call at 6. St. Peter responded, "we're still working on the supply agreements for Galliprant and Entyce." AC ¶ 88; 2015 Q4 Earnings Call at 6.

A second analyst on the call then asked why, if Aratana anticipated filing an administrative NADA by March 2016, commercialization would begin only in late-2016 or

[6] As noted above, the 2015 10-K, like the 2014 10-K, included an express forward-looking statements disclaimer and identified materially identical risk factors. See 2015 10-K at 1, 24–42.

shortly thereafter, given that review of an administrative NADA typically takes only 60 days. AC ¶ 88; 2015 Q4 Earnings Call at 7. St. Peter responded, "for all the reasons that I tried to explain previously, scaling up commercial supply, sequencing the launches, thinking about the—when in the calendar you want to be launching, those are the factors that really—and also getting the actual inventory made and shipped, all the different SKUs. And those are the factors that create that time lag." AC ¶ 88; 2015 Q4 Earnings Call at 7.

On May 5, 2016, Aratana issued a press release attached to a Form 8-K. It disclosed that Aratana had filed its administrative NADA for CVM approval. AC ¶ 89; McDonough Decl. Ex. 25 at 1. The company stated that if ENTYCE were approved by the CVM, Aratana "anticipates commercial availability of Entyce in late-2016 or shortly thereafter." AC ¶ 89; McDonough Decl. Ex. 25 at 1.

On May 6, 2016, Aratana stated the same in its first-quarter Form 10-Q filing. AC ¶ 90; McDonough Decl. Ex. 8 at 23 (the "2016 Q1 10-Q"). The company also disclosed that, during the previous quarter, it "continued to transfer the manufacturing technology processes for . . . ENTYCE to our identified active pharmaceutical ingredient and formulated product contract manufacturers to provide commercial supplies." AC ¶ 90; 2016 Q1 10-Q at 24.

On the same day, Aratana held another earnings call. St. Peter again reiterated the "late 2016 or shortly thereafter" time frame, and stated that Aratana had "commenced the process of hiring a sales organization . . . to support . . . Aratana's anticipated launches of Entyce and Nocita." AC ¶ 92; McDonough Decl. Ex. 26 at 3 (the "2016 Q1 Earnings Call").

3. Early 2017 Release Date

On May 17, 2016, Aratana announced in a press release that the FDA had fully approved ENTYCE for appetite stimulation in dogs. McDonough Decl. Ex. 9 at 1. The company then

stated, revising its timeline once more, that it "intend[ed] to commercially launch Entyce in conjunction with the North American Veterinary Conference in February 2017." *Id.*

On August 4, 2016, Aratana issued another press release attached to a Form 8-K setting forth the same timeline. AC ¶ 93; McDonough Decl. Ex. 27 at 1.

On August 5, 2016, Aratana filed its second-quarter 2016 Form 10-Q. It repeated the company's expectation that ENTYCE would launch commercially in the "first quarter of 2017." AC ¶ 94; McDonough Decl. Ex. 10 at 27 (the "2016 Q2 10-Q"). Aratana also noted that in the second quarter of 2016, it had "continued to transfer the manufacturing technology processes for . . . ENTYCE to our identified active pharmaceutical ingredient ("API") and formulated product contract manufacturers to provide commercial supplies." AC ¶ 95; 2016 Q2 10-Q at 28. Finally, the Form 10-Q also set forth Aratana's near-term plans concerning ENTYCE:

> We intend to make filings to the FDA in the third quarter of 2016, in support of the transfer of API and formulated contract manufacturing to the respective contract manufacturing organizations to be used for the production of launch inventories. FDA approval of these filings are required for product launch.

2016 Q2 10-Q at 28.[7]

The same day, Aratana held its second-quarter 2016 earnings call. St. Peter once again announced that the company anticipated ENTYCE's commercial launch in the first quarter of 2017. AC ¶ 96; McDonough Decl. Ex. 28 at 3. On November 3, 2016, some three months later, Aratana issued another press release announcing the same time frame, provided that "Aratana's supply of Entyce is approved and released." AC ¶ 97; McDonough Decl. Ex. 29 at 1.

On November 4, 2016, Aratana filed its third-quarter 2016 Form 10-Q. On that Form, Aratana addressed ENTYCE's manufacturing status as follows:

---

[7] This statement is conspicuously absent from and unaddressed in both the AC and plaintiffs' brief opposing dismissal.

> During the third quarter of 2016, we continued to transfer the manufacturing technology processes for GALLIPRANT and ENTYCE to our identified active pharmaceutical ingredient ("API") and formulated product contract manufacturers to provide commercial supplies. We have completed the required manufacturing validation work in regards to API for both GALLIPRANT and ENTYCE. We made additional manufacturing filings with the FDA to obtain approvals that are required for commercial launch. Further, we continue to complete the required manufacturing validation work of formulated product and packaging to produce inventory for commercial availability.

AC ¶¶ 98–99; McDonough Decl. Ex. 11 at 25 (the 2016 Q3 10-Q").

Also on November 4, 2016, defendants held a third-quarter 2016 earnings call. In response to a question regarding the "actual launch dates" of GALLIPRANT and ENTYCE, St. Peter gave a detailed response, quoted at length in the AC and reproduced here:

> So we're not changing the timing of what we expect . . . . I think as we've discussed several times over the past few years, there is a lag between the approval and the product launch for these 2 products, because they're new chemical entities, and that takes several months. And so . . . while the manufacturing scale for FDA approval is significant, the scale that is required to support what we believe to be [two very] large commercial products is even larger. And our approach had not been to scale up all the way to that commercial scale at risk. And so what that means is significant post-approval work. And that includes, in some cases, transferring the API or active pharmaceutical ingredient manufacturing. In other cases, moving the formulation of the drug product or packaging and really process improvements. And so when you make those sorts of changes and moves, there's things that require various filings with the FDA to make sure that they understand everything that you're doing, and we need to let those play out before we can actually ship products to the customers. And then, of course, I think some good news, at this point, we believe that we basically made all the necessary filings. It's just a matter of playing those out. And then beyond the regulatory requirements, both Aratana and our collaborators have certain quality standards and procedures that have to be satisfied before product is released to market, and I think that's true for basically all pharmaceuticals. And so that's all what's happening over the next weeks to months to support the time lines we've articulated.

AC ¶ 100; McDonough Decl. Ex. 30 at 8 (the "2016 Q3 Earnings Call").

E. The Alleged Corrective Disclosure

On February 6, 2017, Aratana filed a Form 8-K announcing that the commercial availability of ENTYCE would be pushed back to *late* 2017. AC ¶ 115. This delay, Aratana explained, was the result of the CVM's February 2, 2017 request for additional information from Aratana regarding the company's proposed transfer of ENTYCE manufacturing to a new vendor. *Id.*; *see also* McDonough Decl. Ex. 15 at 3. On this news, shares of Aratana fell 17.93%. AC ¶ 116.

On March 13, 2017, Aratana filed another Form 8-K, reporting $15.1 million in losses in 2016 attributable to impairment charges of intangible assets and inventory adjustments resulting at least in part from the delayed commercial rollout of ENTYCE. AC ¶ 118.

The next day (after the close of the Class Period), Aratana disclosed in its 2016 Form 10-K submission that it had written off $2,639 in process validation batches of ENTYCE and $1,983 in associated manufacturing costs as research and development expenses because those batches could no longer be used as commercial launch inventory. AC ¶ 119; *see also* McDonough Decl. Ex. 3.

Also on March 14, 2017, during the fourth-quarter 2016 earnings call, Tooman announced that Aratana had made inventory adjustments of approximately $2.6 million in inventory intended for an earlier commercial launch, and also had lost a purchase commitment of approximately $2 million. *See* AC ¶ 120. On this news, shares of Aratana's stock dropped another 24%. *Id.* ¶ 121.

F. Post-Class-Period Events

On April 25, 2017, Aratana issued a press release announcing that it had reached an agreement with CVM regarding ENTYCE's manufacture, and believed it would be able to make

ENTYCE commercially available by the fall of 2017. *Id.* ¶ 122. On this news, Aratana's stock price increased approximately 6%. *Id.* ¶ 123.

On May 4, 2017, Aratana filed a press release attached to a Form 8-K announcing that the company had offered and sold approximately $24.4 million worth of common stock in part to support the commercialization of ENTYCE. *Id.* ¶ 124.

On May 9, 2017, Aratana filed its first-quarter 2017 Form 10-Q, reiterating that the company expected ENTYCE to be commercially available by fall 2017. *Id.* ¶ 126.[8]

G. The Individual Defendants' Stock Activity

Plaintiffs allege that the individual defendants made suspicious stock sales, albeit pursuant to pre-set Rule 10b5-1 trading plans, during the Class Period. Tooman, after making no sales before the start of the Class Period, sold approximately $314,175 in Aratana shares across four days in 2015 and 2016. AC ¶¶ 154–56. These sales included one substantial sale on September 9, 2016. *Id.* ¶ 156. St. Peter, meanwhile, after selling 50,000 shares in 2014, sold 300,000 shares during the Class Period, with total proceeds of $1,664,925. *Id.* ¶¶ 157–62.

H. Procedural History

On June 6, 2017, this Court issued a decision consolidating two underlying cases and appointing lead plaintiffs. *See* Dkt. 19. The Court incorporates by reference the prior procedural history set forth in that decision.

---

[8] Defendants note that the FDA ultimately did approve Aratana's PAS on October 13, 2017, without requiring any changes to the manufacturer Aratana had in place when it first submitted the PAS. *See* Dkt. 33 at 2 (citing the declaration of Kevin M. McDonough in support of defendants' reply memorandum, Dkt. 34). However, because the cited document postdates the AC, the Court has not considered this information in resolving the pending motion.

On August 7, 2017, plaintiffs filed the operative AC. Dkt. 22. On October 6, 2017, defendants filed the pending motion to dismiss, Dkt. 28, a memorandum of law in support, Dkt. 29 ("Mem."), and the McDonough Declaration, Dkt. 30. Defendants also filed a letter motion seeking oral argument. Dkt. 27. On November 6, 2017, plaintiffs filed their memorandum of law in opposition to the motion to dismiss, Dkt. 31 ("Opp."), as well as the Hopkins Declaration, Dkt. 32. On November 20, 2017, defendants filed a reply. Dkt. 33.

II. Applicable Legal Standards

A. Standards for Resolving a Motion to Dismiss

To survive a motion to dismiss under Rule 12(b)(6), a complaint must plead "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim will only have "facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). A complaint is properly dismissed where, as a matter of law, "the allegations in a complaint, however true, could not raise a claim of entitlement to relief." *Twombly*, 550 U.S. at 558. Although the court must accept as true all well-pled factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor, *Steginsky v. Xcelera Inc.*, 741 F.3d 365, 368 (2d Cir. 2014), that tenet "is inapplicable to legal conclusions," *Iqbal*, 556 U.S. at 678.

"Securities fraud claims are subject to heightened pleading requirements that the plaintiff must meet to survive a motion to dismiss." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007); *see also Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321–23 (2007).

First, a complaint alleging securities fraud must meet the requirements of Federal Rule of Civil Procedure 9(b). *See ECA & Local 134 IBEW Joint Pension Trust of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 196 (2d Cir. 2009). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). "Allegations that are conclusory or unsupported by factual assertions are insufficient." *ATSI*, 493 F.3d at 99.

Second, such a complaint must comply with the pleading requirements of the Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u–4(b). *See ECA*, 553 F.3d at 196. In particular, where a plaintiff's claims depend upon allegations that the defendant has made an untrue statement of material fact or that the defendant omitted a material fact necessary to make a statement not misleading, the plaintiff "shall specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading." 15 U.S.C. § 78u–4(b)(1). Thus, in order to plead a claim of securities fraud, plaintiffs "must do more than say that the statements . . . were false and misleading; they must demonstrate with specificity why and how that is so." *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004). In addition, the plaintiff "shall, with respect to each act or omission . . . state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2).

B. Elements of Plaintiffs' Claims

Plaintiffs assert claims under §§ 10(b) and 20(a) of the Exchange Act, and Rule 10b-5. AC ¶¶ 194–209.

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance

in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). The SEC's implementing rule, Rule 10b-5, provides that it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." 17 C.F.R, § 240.10b–5.

To state a claim under § 10(b) of the Exchange Act, a plaintiff must adequately plead "(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011) (quotation marks and citation omitted).

To state a claim under § 20(a) of the Exchange Act, "a plaintiff must show (1) a primary violation by the controlled person, (2) control of the primary violator by the defendant, and (3) that the defendant was, in some meaningful sense, a culpable participant in the controlled person's fraud." *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 236 (2d Cir. 2014) (quoting *ATSI*, 493 F.3d at 108) (quotation marks omitted). If a plaintiff has not adequately alleged a primary violation, *i.e.*, a viable claim under another provision of the Exchange Act, then the § 20(a) claims must be dismissed. *See id.*

C. False or Misleading Statements or Omissions

In addition, to survive a motion to dismiss, the complaint must adequately plead "that the defendant made a statement that was 'misleading as to a material fact.'" *Matrixx Initiatives*, 563 U.S. at 38 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)) (emphasis omitted). Significantly, § 10(b) and Rule 10b-5 "do not create an affirmative duty to disclose any and all material information." *Id.* at 44; *see also Basic*, 485 U.S. at 239 n.17. "Disclosure of . . .

information is not required . . . simply because it may be relevant or of interest to a reasonable investor." *Resnik v. Swartz*, 303 F.3d 147, 154 (2d Cir. 2002). An omission of information not affirmatively required to be disclosed is, instead, actionable only when disclosure of such information is "necessary 'to make . . . statements made, in the light of the circumstances under which they were made, not misleading.'" *Matrixx Initiatives*, 563 U.S. at 44 (quoting 17 C.F.R. § 240.10b–5(b)); *see also In re Vivendi, S.A. Sec. Litig.*, 838 F.3d 223, 239–40 (2d Cir. 2016) ("'Pure omissions' of information, absent a duty to disclose, are not actionable. Half-truths, however, 'statements that are misleading . . . by virtue of what they omit to disclose,'" are.)

The materiality requirement, meanwhile, "is satisfied when there is 'a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the total mix of information made available.'" *Matrixx Initiatives*, 563 U.S. at 38 (quoting *Basic*, 485 U.S. at 231–32). As the Supreme Court has explained, a lower standard—such as defining a "material fact" as any "fact which a reasonable shareholder might consider important"—would lead corporations to "bury the shareholders in an avalanche of trivial information[,] a result that is hardly conducive to informed decisionmaking." *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 448–49 (1976). The "materiality hurdle" is, therefore, "a meaningful pleading obstacle." *In re ProShares Trust Sec. Litig.*, 728 F.3d 96, 102 (2d Cir. 2013). However, because of the fact-intensive nature of the materiality inquiry, the Court may not dismiss a complaint "on the ground that the alleged misstatements or omissions are not material unless they are so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance." *ECA*, 553 F.3d at 197 (quotation marks omitted).

D. Statements of Opinion

Like objective statements of material fact, subjective statements of opinion can be actionable as fraud. As the Supreme Court and the Second Circuit have recently clarified, such statements of opinion can give rise to liability in two distinct ways.

First, "liability for making a false statement of opinion may lie if either 'the speaker did not hold the belief she professed' or 'the supporting fact she supplied were untrue.'" *See Tongue v. Sanofi ("Sanofi II")*, 816 F.3d 199, 210 (2d Cir. 2016) (quoting *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1327 (2015)). "It is not sufficient for these purposes to allege that an opinion was unreasonable, irrational, excessively optimistic, [or] not borne out by subsequent events." *In re Salomon Analyst Level 3 Litig.*, 350 F. Supp. 2d 477, 489 (S.D.N.Y. 2004). "The Second Circuit has firmly rejected this 'fraud by hindsight' approach." *Podany v. Robertson Stephens, Inc.*, 318 F. Supp. 2d 146, 156 (S.D.N.Y. 2004) (citing *Stevelman v. Alias Research, Inc.*, 174 F.3d 79, 85 (2d Cir. 1999)).

Second, "opinions, though sincerely held and otherwise true as a matter of fact, may nonetheless be actionable if the speaker omits information whose omission makes the statement misleading to a reasonable investor." *Sanofi II*, 816 F.3d at 210 (citing *Omnicare*, 135 S. Ct. at 1332). To adequately allege that a statement of opinion was misleading through the omission of material information, "[t]he investor must identify particular (and material) facts going to the basis for the issuer's opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Id.* at 209 (quoting *Omnicare*, 135 S. Ct. at 1332). As the Supreme Court has explained, "a reasonable investor, upon hearing a statement of opinion from an issuer, 'expects not just that the issuer

believes the opinion (however irrationally), but that it fairly aligns with the information in the issuer's possession at a time.'" *Id.* at 210 (quoting *Omnicare*, 135 S. Ct. at 1329). "The core inquiry," then, "is whether the omitted facts would 'conflict with what a reasonable investor would take from the statement itself.'" *Id.* (quoting *Omnicare*, 135 S. Ct. at 1329).

The Supreme Court has instructed that this second theory of liability for opinions, based on omissions of material facts that may render a statement of opinion actionable, should not be given "an overly expansive reading"; rather, establishing liability on such a theory "is no small task for an investor." *Id.* (quoting *Omnicare*, 135 S. Ct. at 1332) (quotation marks omitted). "Reasonable investors understand that opinions sometimes rest on a weighing of competing facts, . . . [and do] not expect that every fact known to an issuer supports its opinion statement." *Id.* (quoting *Omnicare*, 135 S. Ct. at 1329) (alterations and quotation marks omitted). "[A] statement of opinion 'is not necessarily misleading when an issuer knows, but fails to disclose, some fact cutting the other way.'" *Id.* (quoting *Omnicare*, 135 S. Ct. at 1329).

Further, the Supreme Court has emphasized, statements of opinion must be considered in the context in which they arise. "'[T]he investor takes into account the customs and practices of the relevant industry,' and . . . 'an omission that renders misleading a statement of opinion when viewed in a vacuum may not do so once that statement is considered, as is appropriate, in a broader frame.'" *Id.* (quoting *Omnicare*, 135 S. Ct. at 1330).

E. The PSLRA Safe Harbor for Forward-Looking Statements

The PSLRA amended the Exchange Act to provide a safe harbor for forward-looking statements. *See* 15 U.S.C. § 78u–5(c). Forward-looking statements are defined as those that contain, among other things, "a projection of revenues, income, [or] earnings," "plans and objectives of management for future operations," or "a statement of future economic

performance." *Id.* § 78u–5(i)(1). A forward-looking statement is not actionable if it "is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton v. Am. Exp. Co.*, 604 F.3d 758, 766 (2d Cir. 2010). Because the statute is written in the disjunctive, statements are protected by the safe harbor if they satisfy any one of these three categories. *Id.* Materiality is defined above; the other two categories are defined as follows:

Meaningful cautionary language: To qualify as "meaningful," cautionary language "must convey substantive information about factors that realistically could cause results to differ materially from those projected in the forward-looking statements." *Id.* at 771 (quoting H.R. Conf. Rep. 104-369, at 43 (1995)). Language that is "vague" or "mere boilerplate" does not suffice. *Id.* at 772. "To determine whether cautionary language is meaningful, courts must first 'identify the allegedly undisclosed risk' and then 'read the allegedly fraudulent materials—including the cautionary language—to determine if a reasonable investor could have been misled into thinking that the risk that materialized and resulted in his loss did not actually exist.'" *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333 (S.D.N.Y. 2014) (quoting *Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002)). Plaintiffs may establish that cautionary language is not meaningful "by showing, for example, that the cautionary language did not expressly warn of or did not directly relate to the risk that brought about plaintiffs' loss." *Halperin*, 295 F.3d at 359.

Actual knowledge: The scienter requirement for forward-looking statements—actual knowledge—is "stricter than for statements of current fact. Whereas liability for the latter requires a showing of either knowing falsity or recklessness, liability for the former attaches only

upon proof of knowing falsity," *Slayton*, 604 F.3d at 773 (quoting *Inst. Invs. Grp. v. Avaya, Inc.*, 564 F.3d 242, 274 (3d Cir. 2009)), pled with the required particularity, 15 U.S.C. § 78u–4(b)(2).

F. Scienter

As noted, Rule 9(b) and the PSLRA require plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u–4(b)(2). "For an inference of scienter to be strong, 'a reasonable person [must] deem [it] cogent and at least as compelling as any opposing inference one could draw from the facts alleged,'" and "the court must take into account plausible opposing inferences." *ATSI*, 493 F.3d at 99 (quoting *Tellabs*, 551 U.S. at 324) (alteration and emphasis in original). The requisite mental state is one "embracing intent to deceive, manipulate, or defraud." *Tellabs*, 551 U.S. at 319 (quotation marks and citation omitted).

Plaintiffs "may satisfy this requirement by alleging facts (1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI*, 493 F.3d at 99. Where plaintiffs do not sufficiently allege that defendants had a motive to defraud the public, they "must produce a stronger inference of recklessness." *Kalnit v. Eichler*, 264 F.3d 131, 143 (2d Cir. 2001).

Recklessness is "a state of mind approximating actual intent, and not merely a heightened form of negligence." *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) (citation and emphasis omitted). To qualify as reckless, defendants' conduct must have been "highly unreasonable" and "an extreme departure from the standards of ordinary care." *Novak v. Kasaks*, 216 F.3d 300, 308 (2d Cir. 2000) (quoting *Rolf v. Blyth, Eastman Dillon & Co.*, 570 F.2d 38, 47 (2d Cir. 1978)) (quotation marks omitted).

Plaintiffs can establish recklessness by adequately alleging that "defendants knew facts or had access to non-public information contradicting their public statements" and therefore "knew or should have known they were misrepresenting material facts." *In re Scholastic Corp. Sec. Litig.*, 252 F.3d 63, 76 (2d Cir. 2001) (citing *Novak*, 216 F.3d at 308). In other words, defendants have acted recklessly if they "understood that their public statements were inaccurate, or were 'highly unreasonable' in failing to appreciate that possibility." *In re Sanofi Sec. Litig. ("Sanofi I")*, 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) (quoting *Novak*, 216 F.3d at 308). "The key, of course, is the honest belief of the management in the truth of information issued to the public." *In re AstraZeneca Sec. Litig.*, 559 F. Supp. 2d 453, 470 (S.D.N.Y. 2008), *aff'd sub nom. State Univ. Ret. Sys. of Ill. v. Astrazeneca PLC*, 334 Fed. App'x 404 (2d Cir. 2009).

In the context of the development of a new drug, "[i]f the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public, then there is scienter." *Id.* Similarly, there is scienter "if the management is reckless in dealing with such adverse facts." *Id.* If, on the other hand, "the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth, then that is not securities fraud." *Id.* (collecting cases).

III. Discussion

The AC fails to state a claim for two independent reasons. First, it fails to adequately allege falsity. Second, it fails to raise a strong inference of scienter. The Court will address each shortcoming in turn.[9]

A. Falsity

Plaintiffs synthesize the AC's theory of falsity as follows: Defendants "repeatedly represented that the Company was on the cusp of achieving—and then had achieved—the approvals necessary for commercialization of [ENTYCE] on the stated timeline," but these statements were misleading because Aratana had not yet secured an FDA-approved third-party manufacturer, making the approval of the NADA "a mere placeholder that required further amendments and approvals to produce commercial quantities of the drug." Opp. at 1–2. The vast majority of the challenged statements, however, constitute puffery, statements of opinion, and/or forward-looking statements that cannot serve as the basis of a federal securities claim. As to the few remaining statements that did purport to relate historical information, plaintiffs either do not premise liability on these statements or have not adequately alleged that, in context, they were false or misleading.

1. Puffery

Statements are mere puffery, and hence non-actionable, when they are "too general to cause a reasonable investor to rely upon them," *ECA*, 553 F.3d at 206; *accord Kleinman v. Elan Corp., plc*, 706 F.3d 145, 153 (2d Cir. 2013); *Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 37 (2d Cir. 2012).

---

[9] In a footnote, defendants claim a third deficiency. They challenge the AC's allegations as to loss causation with respect to certain allegedly actionable statements. *See* Mem. at 10 n.3. Because the Court holds that the AC does not adequately allege falsity or scienter with regard to any statement, there is no occasion to address this separate (and thinly developed) argument.

Several broad assertions by Aratana fall under this doctrine and hence are not actionable. These include that Aratana had "made remarkable progress towards our stated goal of advancing our expanding pipeline towards commercialization," AC ¶ 79, that the company was "confident about and prepared for what lays ahead," *id.*, that Aratana was "proud" to be "on track to have these products reach the market in 2016," *id.* ¶ 83, and that it was "confident in these products and our overall commercialization strategy," *id.* Such statements do no more than place a "positive spin on developments in the [FDA approval] process." *In re EDAP TMS S.A. Sec. Litig.*, No. 14 Civ. 6069 (LGS), 2015 WL 5326166, at *9–10 (S.D.N.Y. Sept. 14, 2015) (statements "indicat[ing] that the [FDA approval] process was 'on track' and making continued 'progress,'" or "declar[ing] defendants' belief that they were 'moving through the approval process in a timely manner,'" "constitute inactionable puffery"); *see also Rombach*, 355 F.3d at 174 ("Up to a point, companies must be permitted to operate with a hopeful outlook: 'People in charge of an enterprise are not required to take a gloomy, fearful or defeatist view of the future; subject to what current data indicates, they can be expected to be confident about their stewardship and the prospects of the business that they manage.'" (quoting *Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129–30 (2d Cir. 1994)); *Lasker v. N.Y.S. Elec. & Gas Corp.*, 85 F.3d 55, 59 (2d Cir. 1996) (statement that company's "business strategies would lead to continued prosperity" constitutes puffery).

2. Opinion Statements and Forward-Looking Statements

As noted, statements of opinion "include subjective statements that reflect judgments as to values that [are] not objectively determinable." *In re Gen. Elec. Co. Sec. Litig.*, 856 F. Supp. 2d 645, 653 (S.D.N.Y. 2012). Statements that "express expectations about the future rather than presently existing, objective facts" are also statements of opinion. *Fialkov v. Alcobra Ltd.*, No. 14 CIV. 09906 (GBD), 2016 WL 1276455, at *6 (S.D.N.Y. Mar. 30, 2016). Such statements,

often marked by phrases such as "I believe," are inactionable so long as the speaker actually held the belief professed, did not supply an untrue supporting fact, and did not omit information rendering the statement misleading. *See Omnicare,* 135 S. Ct. at 1326–27. Forward-looking statements, meanwhile, include "plans and objectives of management for future operations." 15 U.S.C. § 78u–5(i)(1). A forward-looking statement is not actionable if it "is identified and accompanied by meaningful cautionary language or is immaterial or the plaintiff fails to prove that it was made with actual knowledge that it was false or misleading." *Slayton*, 604 F.3d at 766.

Nearly all of defendants' statements as to their expectations regarding FDA approval and the timeline for ENTYCE's commercial release were framed as opinions, forward-looking statements, or both. *See, e.g.*, AC ¶ 80 ("[T]he Company anticipates submitting an NADA [for ENTYCE] in early 2016, which if approved, is expected to enable the company to commence commercialization of the product in mid-2016 or shortly thereafter."); *id.* ¶ 83 ("[W]e believe that we are on track to have these products reach the market in 2016 . . . . We very much look forward to launching these products next year."); *id.* ¶ 85 ("If approved by the CVM, Aratana anticipates commercial availability of ENTYCE in late-2016 or shortly thereafter."); *id.* ¶ 87 ("We believe we have or will have sufficient supply of formulated drugs to meet our commercial forecast."); *id.* ¶ 94 ("We intend to commercially launch ENTYCE in the United States in the first quarter of 2017 in conjunction with the North American Veterinary Conference and other major veterinary conferences."); *id.* ¶ 100 ("[W]e believe that we basically made all the necessary filings. It's just a matter of playing those out.").

Further, defendants accompanied these statements with a formidable array of cautionary disclosures. *See id.* ¶¶ 105–13. From the start of the Class Period, defendants repeatedly warned

that (1) Aratana was dependent on third-party manufacturers, (2) third-party manufacturers require FDA approval, (3) Aratana's third-party manufacturers might need to increase their manufacturing capacities to scale up for commercial release, and (4) the failure of a third-party manufacturer to secure FDA approval might impede the company's ability to bring products to market. *See, e.g.*, 2014 10-K at 38–39; 2015 10-K at 30–31.

Plaintiffs do not—and cannot—dispute the foregoing. *See* Opp. at 14, 17.[10] Rather, they argue that defendants' statements, although couched as opinions or forward-looking statements, contained embedded assertions of fact that defendants knew to be false. *See id.* at 14–19. Specifically, plaintiffs contend that even as defendants articulated optimistic timelines for ENTYCE's commercialization, they secretly knew, but failed to disclose, that commercialization would require another round of FDA approval necessitated by Aratana's failure to find a satisfactory manufacturer. *See id.* at 2–3.

This argument badly mischaracterizes defendants' statements. First, read in context, the statements did not "downplay[] the centrality of FDA manufacturing approval" or conceal "an entirely separate stage of FDA approval that was essential for commercialization." Opp. at 3. To the contrary, from the very start of the Class Period, Aratana disclosed that commercialization of ENTYCE might require additional steps beyond mere NADA approval, including, potentially, a change in manufacturer and CVM approval. *See* 2014 10-K at 34 (disclosing that the development of products including ENTYCE depends on "the ability of us or our third-party

[10] Plaintiffs make the cursory suggestion that Aratana's cautionary language was not meaningful, in that it did not specifically address the undisclosed risk, *see* Opp. at 18, but that is incorrect: Defendants expressly warned that the CVM might not approve their contract manufacturers for products including ENTYCE. *See* 2014 10-K at 38–39. The risk that ultimately materialized—in which the CVM requested additional information about a contract manufacturer—was clearly encompassed by defendants' cautionary disclosures.

manufacturers to manufacture supplies . . . and to develop, validate and maintain commercially viable manufacturing processes that are compliant with [cGMP]"); *id.* at 38–39 ("If the CVM . . . does not approve our contract manufacturers' facilities used for the manufacture of our product candidates, or if [the CVM] withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would adversely impact our ability to develop and obtain regulatory approval for or market our product candidates, if approved."); *id.* at 39 ("[T]o manufacture our product candidates in the quantities that we believe would be required to meet anticipated market demand, our third-party manufacturers may need to increase manufacturing capacity, which could involve significant challenges and may require additional regulatory approvals.").

Further, once Aratana began to transfer its manufacturing process to a new facility, it informed investors that the transfer had begun, *see* 2015 10-K at 9 ("We are currently transferring the manufacturing technology process for . . . ENTYCE and scale-up required for commercialization."), and then updated investors as to its plan to seek regulatory approval, *see* 2016 Q2 10-Q at 28 ("We intend to make filings to the FDA in the third quarter of 2016, in support of the transfer of API and formulated contract manufacturing to [new manufacturers] for the production of launch inventories. FDA approval of these filings are required for product launch."). Once the company had done so, it then informed investors of this. *See* 2016 Q3 10-Q at 25 ("We made additional manufacturing filings with the FDA to obtain approvals that are required for commercial launch.").

Defendants therefore overtly disclosed not only that ENTYCE would be produced by contract manufacturers, who would typically require FDA approval, but also, more specifically, that Aratana in fact planned to seek (and eventually did seek) such approval for ENTYCE's

commercial manufacturer. Given these comprehensive disclosures of this regulatory risk, the mere fact that the risk materialized cannot support a claim under the Exchange Act. *See Acito v. IMCERA Grp.*, 47 F.3d 47, 53 (2d Cir. 1995) ("[D]efendants' lack of clairvoyance simply does not constitute securities fraud.").

For the same reasons, defendants cannot be said to have concealed a risk that had already metastasized into reality. *Contra* Opp. at 11–13 & n.3. First, the AC does not allege that, before February 2, 2017, the CVM had already requested additional information from Aratana. And second, to the extent plaintiffs allege that the risk that had already materialized was Aratana's lack of a suitable manufacturer, defendants disclosed that fact as early as May 8, 2015, when St. Peter explained that Aratana was working to secure a commercial supply of ENTYCE. *See* Q1 2015 Earnings Call at 4; *see also* 2015 Q2 Earnings Call at 8 (statement by St. Peter that the company was working to secure a commercial supply agreement with a contract manufacturer). Given that Aratana had already notified investors that a transfer of manufacturing could require CVM approval, *see* 2014 10-K at 39, the company's statements satisfactorily armed investors with all the information necessary to evaluate the risks associated with the anticipated timeline. *See Sanofi I*, 87 F. Supp. 3d at 540 (where a "reasonable investor had reason to know" that pharmaceutical company's clinical trial methodology was not "gold standard," "[s]uch an investor could reasonably infer that the study design might impede or delay FDA approval").

In short, because defendants amply disclosed both the need for a new commercial-scale manufacturer and the fact that such a transfer of manufacturing responsibility might require additional regulatory approval, it is clear from the face of the AC and materials cognizable thereunder that defendants did not misrepresent or conceal from stockholders the possibility (or

necessity) of a new manufacturer, of additional CVM inquiries, or of any concomitant delays in commercialization.[11]

Defendants' opinion and forward-looking statements are not actionable for a second reason. Even if these statements had contained embedded misleading statements, plaintiffs do not adequately allege that defendants at the start of the Class Period *knew* the facts that made them so: to wit, that the projected timelines for ENTYCE's commercial release were overly optimistic, or that the CVM eventually would request more information regarding Aratana's commercial manufacturer. In other words, plaintiffs have failed to allege adequately that defendants' opinion statements did not "fairly align[] with the information in [their] possession at the time," *Omnicare*, 135 S. Ct. at 1329, or that their forward-looking statements were knowingly false, *see Slayton*, 604 F.3d at 773.

As developed in greater detail in connection with the discussion below of scienter, there are simply no concrete allegations suggesting that defendants knew, let alone *when* they knew, that the CVM would request additional information about Aratana's new contract manufacturer, or that defendants actually disbelieved their own estimates as to ENTYCE's commercialization date. Plaintiffs instead appear to argue that defendants' serial revisions of the commercialization timeline demonstrate their culpable knowledge. *See* AC ¶ 130; Opp. at 12. But that contention amounts to claiming "fraud by hindsight," in which plaintiffs "collapse allegations of the

[11] Plaintiffs separately challenge defendants' repeated statements that a NADA, "if approved, would allow us to commence commercialization of the product." Plaintiffs argue that these opinion and forward-looking statements falsely implied that NADA approval was the *only* obstacle to commercialization. *See, e.g.*, Opp. at 11 (quoting AC ¶ 77). In fact, given the extensive disclosures reviewed above, a reasonable investor would have understood these subjunctive statements to indicate that NADA approval was a necessary condition, but not the only condition, required for commercialization.

objective wrongness of the opinions with claimed subjective insincerity." *Podany*, 318 F. Supp. 2d at 156. As a matter of law, that dog won't hunt. *See id.*

3. The Remaining Challenged Statements

While the foregoing discussion of puffery, opinion statements, and forward-looking statements inters plaintiffs' claims based on the vast majority of statements in the AC, several statements at issue do purport to relate historical facts so as to require a separate analysis. These include defendants' statements that they were "working to complete the commercial supply agreement [on ENTYCE]," AC ¶ 79; that they were "transferring the manufacturing technology process . . . for ENTYCE and scale-up required for commercialization," *id.* ¶ 87; that they had "commenced the process of hiring [a] sales organization" to support ENTYCE's commercial launch, *id.* ¶ 92; that they were working to "complete the required manufacturing validation work of formulated product and packaging to produce inventory for commercial availability," *id.* ¶ 98; and that they had "completed the required manufacturing validation work in regards to API for . . . ENTYCE," *id.*

With respect to these statements, however, the AC contains only generalized, conclusory allegations of falsity. Indeed, apart from the first two statements, which concern the transfer of ENTYCE's manufacturing process, the AC does not directly challenge these statements at all. There is no claim that defendants misled investors as to their failure to hire a sales organization, develop appropriate packaging, or find a suitable manufacturer specifically for their active ingredients (as opposed to formulated product). Plaintiffs' allegation instead is that defendants failed to alert investors to a foreseeable regulatory delay occasioned by a transition to a commercial manufacturer.

As for the statements related to *that* alleged failure—*i.e.*, that defendants were working toward a commercial supply agreement and transferring the manufacturing process—the AC

does not contain any particularized allegations supporting that defendants' statements were false. It does not allege that defendants, in fact, were *not* working to complete a commercial supply agreement, or that defendants had *not* begun the transfer process. At most, plaintiffs allege that these statements falsely implied that Aratana already had an FDA-compliant facility in place to produce commercial quantities of ENTYCE. *See* Opp. at 2. But the statements express precisely the opposite. And defendants repeatedly precluded the false implication that plaintiffs conjure by explaining that Aratana was transferring the manufacturing process specifically because its clinical-trials manufacturer could not scale up to commercial distribution. *See* AC ¶¶ 88, 100. Accordingly, there is no theory under which defendants may be held liable for these statements.

B. Scienter

To plead scienter, plaintiffs must adequately allege facts showing either that defendants (1) had "motive and opportunity" to make false or misleading statements or (2) engaged in "conscious misbehavior or recklessness" when they made such statements. *ATSI*, 493 F.3d at 99. "Sufficient motive allegations 'entail concrete benefits that could be realized by one or more of the false statements and wrongful nondisclosures alleged.'" *Kalnit*, 264 F.3d at 139 (quoting *Novak*, 216 F.3d at 307). "Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from the fraud." *Id.*

1. Motive

Plaintiffs offer three theories of motive: that defendants (1) enriched themselves through suspicious securities transactions; (2) sought to avoid principal payments under Aratana's loan agreement; and (3) sought to ensure the success of a round of public offerings in Aratana stock. None of these theories can sustain the AC's claim of scienter.

a. Securities Transactions

Plaintiffs first allege that the individual defendants—corporate insiders privy to information on ENTYCE's prospects for success—profited from suspiciously timed securities transactions. "Unusual insider sales at the time of the alleged withholding of negative corporate news may permit an inference of bad faith and scienter." *Scholastic Corp.*, 252 F.3d at 74 (quotation marks omitted). "Factors considered in determining whether insider trading activity is unusual include the amount of profit from the sales, the portion of stockholdings sold, the change in volume of insider sales, and the number of insiders selling." *Id.* at 74–75.[12]

It is undisputed that the individual defendants transacted in Aratana securities during the Class Period, pursuant to Rule 10b5-1 trading plans. *See* AC ¶¶ 154, 157. SEC filings indicate that during the Class Period, St. Peter acquired 237,400 shares of common stock and 345,000 options, and sold 300,000 shares, and that Tooman acquired 65,850 shares of common stock and 102,500 options, and sold 39,676 shares. *See* McDonough Decl. Exs. 41–46, 53–58.

At the outset, the parties disagree as to the significance of the fact that the Aratana stock and stock options that the individual defendants acquired during the Class Period, in which the individual defendants had the present or future right to trade, were acquired at no cost. *See id.* Exs. 41, 45, 55, 58. Plaintiffs argue that shares obtained for free should be disregarded in determining whether the individual defendants' trading activity gives rise to an inference of scienter. *See* Opp. at 21 (citing *Freudenberg v. E*Trade Fin. Corp.*, 712 F. Supp. 2d 171, 201

[12] The AC perplexingly omits the individual defendants' total holdings of Aratana stock at the beginning of the Class Period, as well as any profits they made. *See* AC ¶¶ 153–66. Plaintiffs' failure to allege defendants' profits would itself be a sufficient basis to reject an inference of motive. *See Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011). Nevertheless, the parties agree that the Court may take judicial notice of the individual defendants' SEC Forms 4, and these forms supply the missing information as to total holdings and profits. *See* McDonough Decl. Exs. 31–58; Opp. at 20 n.7.

(S.D.N.Y. 2010)); *see also In re EVCI Colls. Holding Corp. Sec. Litig.*, 469 F. Supp. 2d 88, 100 (S.D.N.Y. 2006). Defendants, for their part, cite the "weight of authority" holding that zero-cost stock and option acquisitions should be taken into account in comparing the volume of an insider's sales to his overall shareholdings. *See* Mem. at 19–20 & n.8 (quoting *Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009)); *see also Acito*, 47 F.3d at 54 (calculating total volume of shareholdings by including unvested options).

Although the Second Circuit has not answered this question definitively, there is wisdom, in this Court's view, to the approach taken by Judge Scheindlin in *In re eSpeed, Inc. Securities Litigation*, 457 F. Supp. 2d 266 (S.D.N.Y. 2006). There, Judge Scheindlin adopted the Ninth Circuit's nuanced approach of distinguishing between *vested* stock options (*i.e.*, exercisable stock options) and unvested stock options, which cannot be converted into shares and sold immediately. *Id.* at 290–91 (citing *In re Silicon Graphics Sec. Litig.*, 183 F.3d 970, 986–87 (9th Cir. 1999)). Under this approach, the decisive question in assessing whether an insider's sales are indicative of scienter is how many shares the insider sold during the class period relative to the total number of shares that he or she *could have* sold. Such a number appropriately captures not only the fact of sales, but also the extent to which the insider availed himself or herself of, or forwent, the opportunity to turn a profit before disclosure of concealed bad news. Accordingly, the Court will include among defendants' total shareholdings both zero-cost shares of common stock and vested options, but not unvested options.

Here, it appears that at least some of the options acquired by the individual defendants vested within the Class Period. *See* McDonough Decl. Exs. 41 n.2, 55 n.1.[13] While the parties have not provided the number of options that vested during the Class Period, that number

[13] The options acquired in 2017 did not vest until January 2018. *See id.* Exs. 45 n.2, 58 n.1.

appears to be slightly more than 40,000 for St. Peter, and slightly more than 14,375 for Tooman. Counting these exercisable options as shares, St. Peter's total shares decreased during the Class Period by approximately 22,600 shares, or approximately 1.9% of the 1,170,716 shares and options with which he entered the Class Period, while Tooman's total shares *increased* during the class period by approximately 40,549 shares, or approximately 15.8% of the 255,858 shares and options with which he entered the Class Period. St. Peter's minuscule overall reduction in holdings, along with Tooman's significant increase in holdings, undermine an inference that defendants, through their sales, sought to capitalize on the necessarily time-limited artificial inflation of Aratana's stock price. *See In re Bristol Myers-Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) (increased holdings are "wholly inconsistent with fraudulent intent").

In any event, the overall circumstances surrounding the individual defendants' sales so clearly do not plausibly support inferring scienter that the choice among these methodologies is ultimately academic. Even assuming that the Court were to disregard all options held by the individual defendants (vested as well as unvested) in calculating the extent of insider sales during the class period, the individual defendants' trading still would not establish motive. That is so for three reasons. First, even on plaintiffs' methodology, St. Peter's holdings declined by a bare 9%, while Tooman's holdings increased by approximately 34%. *See Acito*, 47 F.3d at 54 (sales representing less than 11% of defendant's holdings did not support strong inference of intent to deceive); *Glaser*, 772 F. Supp. 2d at 593 ("It defies reason that an entity looking to profit on a fraudulently inflated stock price would hold close to ninety percent of its shares as prices fell, *while knowing that the information illuminating the fraud was seeping into the market.*").

Second, contrary to plaintiffs' claim, the timing of defendants' sales, fairly analyzed, is not suspicious. It does not give rise to an inference of insider knowledge, at the time of the sales,

of material undisclosed bad news. For instance, plaintiffs contend that St. Peter sold "150,000 shares in late 2016, just before the end of the period—'late 2016'—when Defendants had professed that ENTYCE would have a commercial launch." Opp. at 20. But St. Peter sold these shares in August and December 2016—*after* Aratana had already disclosed (on August 5, 2016) that it intended to file a PAS regarding the transfer of ENTYCE manufacturing. *See* 2016 Q2 10-Q at 28. For the same reason, defendants' assertion that "Tooman sold 30,000 shares less than two months before the Company disclosed the need for a PAS to investors," Opp. at 20, is simply wrong: Tooman sold these shares in September 2016, after defendants' August 5, 2016 disclosure. *See* McDonough Decl. Ex. 57.

Third, as a general matter, "[t]rades made pursuant to a Rule 10b5-1 trading plan do not give rise to a strong inference of scienter." *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 585 (S.D.N.Y. 2014). It is true, as plaintiffs suggest, that the mere existence of a trading plan will not defeat an otherwise strong inference of scienter where, as here, the plans were entered into during the Class Period. *See id.*; *see also Freudenberg*, 712 F. Supp. 2d at 200–01. But the AC fails to raise any inference that the plans were themselves suspect: Apart from the allegations of suspicious timing just addressed, the AC relies only on recent publications suggesting that trading plans may be abused. *See* AC ¶¶ 165–66. Such generalized allegations do not give rise to a strong inference of scienter. *See Lululemon*, 14 F. Supp. 3d at 585 (no inference of scienter where the complaint "pleads no facts that even remotely suggest that [defendant] entered into the Plan [during the Class Period] 'strategically' so as to capitalize on insider knowledge.").

b. The Loan Agreement

Plaintiffs' second argument as to motive is that the individual defendants lied about ENTYCE to allow Aratana to defer principal payments on the company's $40 million loan. Plaintiffs argue that defendants maintained the alleged ENTYCE fraud so as to convince lenders

that ENTYCE had been "fully approved," thereby avoiding damaging early principal payments under the terms of the loan agreement. *See* AC ¶¶ 167–71; Opp. at 22.

"[C]ourts in this Circuit have consistently held that allegations that a defendant was motivated to commit securities fraud by a desire to reduce its debt burden . . . are insufficient to raise a scienter inference." *In re GeoPharma, Inc. Sec. Litig*, 399 F. Supp. 2d 432, 450 (S.D.N.Y. 2005) (citing *San Leandro Emergency Med. Grp. Profit Sharing Plan v. Philip Morris Cos.*, 75 F.3d 801, 814 (2d Cir. 1996)). And the AC lacks any factual allegations to support this theory of motive, aside from the mere existence of the loan agreement itself. AC ¶¶ 167–71. Accordingly, lacking any concrete factual allegations to support this theory of motive to hide the company's ostensible inability to timely line up a ready manufacturer, the AC's claim that Aratana "sought to reduce its cash outlays for debt service" is insufficient to support an inference of scienter. *GeoPharma*, 399 F. Supp. 2d at 450 (citing *In re Duane Reade Inc. Sec. Litig.*, No. 02 Civ. 6478 (NRB), 2003 WL 22801416, at *8–9 (S.D.N.Y. Nov. 25, 2003)).

c. The Public Offerings

Plaintiffs' final argument as to motive is that the individual defendants perpetrated the alleged ENTYCE fraud to ensure a high share price for the company's sales offerings, which in turn would give Aratana the liquidity it needed to satisfy the terms of the loan agreement. *See* AC ¶¶ 172–77; Opp. at 22–23. But as noted, a mere desire to reduce debt outlays, without more, is insufficient to establish motive. And the same is true of "[a]ny potential motive to keep the share price high in order to have a more successful [offering]," which is "just an example of a generalized motive that any officer or director who desires to operate a successful company will have." *AstraZeneca*, 559 F. Supp. 2d at 469. After all, "[i]t is very common for companies to have secondary [offerings], and any officer or director would wish the stock price to be as high as possible during such [an offering]." *Id.*; *see also Russo v. Bruce*, 777 F. Supp. 2d 505, 520

(S.D.N.Y. 2011) (desire to "inflate the price of [the Company's] stock so that the Company could sell such stock to raise cash . . . comfortably fits within the set of universal corporate motivations that are inadequate to sustain a securities fraud complaint").

2. Conscious Misbehavior or Recklessness

Because plaintiffs have failed to establish motive, they bear a "correspondingly greater" burden in alleging conscious misbehavior or recklessness. *ECA*, 553 F.3d at 198–99 (quotation marks omitted). The AC falls well short.

First, the AC lacks non-conclusory allegations to support the inference that defendants knowingly withheld or misrepresented information in their possession. For instance, the AC does not cite any internal documents or confidential witness statements tending to suggest that defendants knowingly deceived shareholders. Indeed, the AC lacks any concrete allegations whatsoever regarding defendants' knowledge, apart from the information defendants themselves disclosed. *See* AC ¶¶ 130–50; Opp. at 24. Absent concrete allegations as to defendants' knowledge, the AC cannot generate a strong inference of scienter.

Second, plaintiffs argue that defendants' repeated delays of ENTYCE's commercial release "disguise[ed] the fact there was no adequate facility to launch ENTYCE." AC ¶ 130. It is true that a defendant acts with scienter "[i]f the management knows that certain facts will necessarily prevent the regulatory approval . . . and conceals these facts from the investing public." *AstraZeneca*, 559 F. Supp. 2d at 470. But there is no scienter where "the management of the company releases positive reports about the drug to the public along the way which the management honestly believes to be true, and where there is no reckless disregard for truth." *Id.*

Here, for much the same reasons that it fails to plead falsity with respect to defendants' projections about FDA approval, *see supra* Part III.A.2, the AC also fails to adequately plead scienter. *See, e.g.*, *Sanofi I*, 87 F. Supp. 3d at 534 (noting falsity and scienter requirements are

essentially identical with regard to opinion statements). As explained, the AC's allegations as to defendants' knowledge are utterly conclusory and premised entirely on defendants' own public disclosures.

Moreover, several allegations in the AC tend to suggest the *absence* of fraudulent intent. For instance, in anticipation of a February 2017 commercial launch, defendants voluntarily hired a sales team and spent millions of dollars developing ENTYCE inventory, which they were ultimately forced to write off. *See* AC ¶¶ 72, 92. Viewed in conjunction with the absence of any direct evidence of defendants' guilty knowledge, these facts cast grave doubt on plaintiffs' allegations that defendants knew all along that a February 2017 release date was impossible. *See AstraZeneca*, 559 F. Supp. 2d at 471 (no inference of scienter where complaint alleged no "red flag" indicating management's knowledge and other facts, such as regulatory approval of drug for other uses, made it reasonable for management to believe in their product).

In the end, although the facts alleged in the AC do not preclude an inference of fraudulent intent, the far more compelling inference from the facts pled is that defendants believed in good faith that they would obtain regulatory approval and commercialize on the anticipated timelines, but, upon encountering setbacks and changes in marketing strategy, timely updated the market. For that reason, plaintiffs have failed to raise a strong inference of scienter. *See ATSI*, 493 F.3d at 99, 104.[14]

[14] Plaintiffs also suggest that Aratana's substantial revenue projections for ENTYCE and alleged lack of compliance with FDA regulations support an inference of scienter. *See* AC ¶¶ 141–50; Opp. at 24–25. But plaintiffs fail to explain either how an expectation of large revenue gives rise to an inference of fraudulent intent, or how defendants ostensibly breached FDA regulations, let alone knowingly concealed their noncompliance.

C. Section 20(a) Claims

Plaintiffs also bring claims against the individual defendants under § 20(a) of the Exchange Act. AC ¶¶ 204–09. To state a claim under § 20(a), plaintiffs must adequately allege "a primary violation by the controlled person." *Carpenters Pension Tr. Fund*, 750 F.3d at 236 (quoting *ATSI*, 493 F.3d at 108). Because plaintiffs have not done so, their § 20(a) claims must also be dismissed. *See, e.g.*, *In re Lions Gate Entm't Corp. Sec. Litig.*, No. 14 Civ. 5197 (JGK), 2016 WL 297722, at *18 (S.D.N.Y. Jan. 22, 2016) (dismissing § 20(a) claim based on failure to adequately allege a primary violation).

CONCLUSION

For the foregoing reasons, the Court dismisses the AC in its entirety, with prejudice. The Clerk of Court is respectfully directed to terminate the motions pending at docket numbers 27 and 28 and to close this case.

SO ORDERED.

Paul A. Engelmayer
United States District Judge

Dated: June 11, 2018
New York, New York